IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
WESTERN DIVISION

STEPHANIE KNOTH **PLAINTIFF**

VS. **CAUSE ACTION NO.: 5:18-CV-49-DCB-MTP**

DR. STEPHEN P. KEITH, ET AL. **DEFENDANTS**

Order

This matter is before the Court on Apollo Endosurgery US, Inc., ("Apollo")'s Motion for Reconsideration. [ECF No. 159]. Having read the Motion, the submissions of the parties, applicable statutory and case law, the record, and being otherwise fully informed of the premises, the Court denies the Motion for Reconsideration.

Background

This is a medical malpractice and products liability dispute, arising from the implant of an ORBERA® gastric balloon manufactured by Apollo. Dr. Stephen Keith implanted the ORBERA® balloon in Ms. Knoth ("Plaintiff"). Soon after Plaintiff experienced complications which ultimately led to the removal of the ORBERA®. Apollo filed a Motion for Summary Judgment on the two parallel state claims: (1) manufacturing defect and (2) breach of express warranty. [ECF No. 126]. On December 9, 2020, the Court denied

Apollo's Motion for Summary Judgment. [ECF No. 149]. Apollo now requests that the Court reconsider its Order denying Apollo's Motion for Summary Judgment [ECF No. 149], and requests that the Court hold a pretrial hearing pursuant to Fed. R. Evid. 104(b) to consider whether Plaintiff has sufficient evidence to support her manufacturing defect and express warranty claims.

One week following the Court's denial of Summary Judgment [ECF No. 149], Plaintiff withdrew her expert, Dr. Diarra. Apollo contends that Plaintiff cannot prove her case at trial without Dr. Diarra. Apollo further requests that the Court address arguments which were "left unresolved by the Court— including the absence of admissible manufacturing defect evidence (even if spoliation inference is permitted); the consideration of Ms. Knoth's medical device report; whether a breach of warranty has in fact occurred; the FDA's approval, and thus preemption, of the patient brochure's list of complications; and the application of the learned intermediary doctrine to the Plaintiff's breach of warranty claim." [ECF No. 160] at 1.

Analysis

The Court may revise an interlocutory order at any time for any reason before it enters a final judgment. Fed. R. Civ. P 54(b); United States v. Renda, 709 F.3d 472, 479 (5th Cir. 2013). An order denying a motion for summary judgment does not adjudicate all

claims or decide the rights and liabilities of all parties and is therefore interlocutory. Fed. R. Civ. P. 54(b).

Apollo argues that without Dr. Diarra, Plaintiff cannot prove her case at trial. The Court did not rely on Dr. Diarra's opinions when denying summary judgment [ECF No. 149]; her affidavit does not mention Apollo. [ECF NO. 136-11]. Dr. Diarra's re-designation as a consulting expert does not impact the Court's decision to deny summary judgment.

Apollo argues that "the Court erred in finding that Dr. Keith was acting as Apollo's apparent agent." [ECF No. 160] at 3-4. The Court found that "questions of apparent authority are questions of fact, and typically are for the jury to determine." [ECF No. 149] at 6 (citing Wood v. Holiday Inns. Inc., 508 F.2d 167, 176(5th Cir. 1975). "The manifestations of the principal may be made directly to the third person, or may be made to the community, by signs or advertising." Gizzi v. Texaco, 437 F.2d 308, 309 (3d Cir. 1971). The Court did not conclude that Dr. Keith was acting as an apparent agent. Instead, the Court concluded that "Apollo's advertising of the ORBERA® device creates a factual issue regarding Dr. Keith's apparent authority"; thus summary judgment is not appropriate. [ECF No. 149] at 7.

Apollo argues that the Court should not consider the Medical Device Report ("MDR") in determining whether Plaintiff has met her

burden of proof, claiming that the evidence is inadmissible at trial. Apollo's Motion states "the Plaintiff relied heavily on Apollo's FDA-required investigation report pertaining to Mrs. Knoth's device in order to avoid summary judgment." [ECF No. 160] at 5. Apollo's Motion for Reconsideration is unclear as to which report it references. There are two reports (1) a Form 3500A MDR sent to the Food and Drug Administration ("FDA") made by Dr. Keith [ECF No. 136-6] and (2) an internal complaint form [ECF No. 145]. The federal statute governing the submission of MDRs states:

> No report made under paragraph (1) by--
>
> **(A)** a device user facility,
>
> **(B)** an individual who is employed by or otherwise formally affiliated with such a facility, or
>
> **(C)** a physician who is not required to make such a report,
>
> shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

21 U.S.C. § 360i(b)(3).

The Court cited Apollo's Form 3500A MDR for the purpose of supporting that the ORBERA® balloon was not returned to Apollo. Apollo's Form 3500A MDR is not the type of MDR that is inadmissible under Section 360i(b)(3) because it was not made by: (A) a device user facility (i.e., the hospital), (B) an individual employed by or affiliated with such a facility, or (C) a physician not required to make such a report. See 21 U.S.C. § 360i(b)(3). Apollo's Form

3500A MDR attributes a "Company Representative" and a "Health Professional" as report sources. [ECf No. 136-6] at 2. If properly identified and submitted, Apollo's 3500A Form MDR could be received as a business record.

The Court's Order cited the internal complaint form and stated that the information contained therein suggests that the device either caused or could cause serious injury. [ECF No. 149] at 8. The internal complaint form is not inadmissible under U.S.C. § 360i(b)(3) because it was not made by: (A) a device user facility (i.e., the hospital), (B) an individual employed by or affiliated with such a facility, or (C) a physician not required to make such a report. See 21 U.S.C. § 360i(b)(3). The internal complaint was made by Apollo, the manufacturer. If properly identified and submitted, the internal complaint could be received as a business record.

Apollo argues that even accepting an adverse inference due to Apollo's spoliation of evidence and consideration of the MDR, Plaintiff is still unable to proceed in a manufacturing defect claim because the Plaintiff must establish that a manufacturing defect in the device caused the injury. [ECF NO. 160] at 5. The Court found: (1) Dr. Keith disposed of evidence that is at the core of Plaintiff's manufacturing defect claim; (2) Apollo's internal investigation report suggests that the device caused the

injury; and (3) that Dr. Keith knowingly had a duty to send the device to pathology. [ECF No. 149] at 8. A party cannot simply circumvent liability by disposing of key evidence. See e.g., Sec. Alarm Fin. Enterprises, L.P. v. Alarm Prot. Tech., LLC, 2016 WL 7115911, at *6 (D. Alaska 2016)(spoiling party "should not be able to benefit from its wrongdoing"). There are enough material facts at issue for the manufacturing defect claim to survive summary judgment.

The Court found an issue of material fact concerning the breach of express warranties claim because Dr. Sharlin concluded "that the ORBERA® brochure and the 2016 ORBERA® website were not reviewed or approved by the FDA and opined[d] that express warranties for the device were breached." [ECF No. 159] at 10. There is a dispute over Dr. Sharlin's expert opinion on the breach of the express warranties. As stated in the Order, "this dispute creates a triable issue of material fact." [ECF No. 149] at 11; see Stubblefield v. Suzuki Motor Corp., No. 3:15-CV-18-HTW-LRA, 2018 WL 4764175, at *7 (S.D. Miss. Sept. 30, 2018) (recognizing expert disputes must be decided by a jury). Furthermore, a jury could find that the statements made go beyond the FDA's approval. See Wildman v. Medtronic, Inc., 874 F.3d 862, 870 (5th Cir. 2017).

Apollo reasserts that Dr. Keith was a learned intermediary and therefore Plaintiff cannot establish a breach of warranty.

[ECF No 160] at 10. The learned intermediary doctrine is a products liability defense that explains drug manufacturers are required only to warn the prescribing physician who acts as a learned intermediary between the manufacturer and consumer. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir.1974). Dr. Keith's status as an apparent agent of Apollo is a fact question for the jury. If Dr. Keith is found to be an apparent agent of Apollo, then he would be acting as an agent not a learned intermediary; thus, there is an issue of fact for the jury to determine.

Apollo has neither "clearly established" that the Court's ruling was manifestly erroneous, nor offered newly discovered evidence justifying reconsideration. Matter of Life Partners Holdings, Inc., 926 F.3d 103, 128 (5th Cir. 2019). The Court denied summary judgment because issues of material fact remain, and for the same reason Apollo's Motion for Reconsideration [ECF No. 159] is denied.

In the alternative, Apollo has requested that the Court hold a pretrial hearing pursuant to Fed. R. Evid. 104(b) to determine whether there is sufficient evidence to support Plaintiff's claims. [ECF No. 159]. Rule 104(b) states:

> When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist. The court may admit the

proposed evidence on the condition that the proof be introduced later.

"Under Rule 104(b), the trial court must admit the evidence if sufficient proof has been introduced so that a reasonable juror could find in favor of authenticity or identification." United States v. Isiwele, 635 F.3d 196, 199 (5th Cir. 2011). "Whether a sufficient factual foundation has been established to permit the introduction of an exhibit is a decision best reserved for trial." Marine Power Holding, L.L.C. v. Malibu Boats, LLC, No. CV 14-912, 2016 WL 4218217, at *2 (E.D. La. Aug. 8, 2016. Apollo's request for a pretrial hearing is denied.

Accordingly,

IT IS HEREBY ORDERED that Apollo's Motion for Reconsideration [ECF No. 159] is DENIED.

FURTHER ORDERED that Apollo's Motion for a Pretrial Hearing Pursuant to Fed. Rule Evid. 104(b) is DENIED.

SO ORDERED, this the 1st day of February, 2021.

/s/ David Bramlette
UNITED STATES DISTRICT JUDGE